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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

Shipping Address (FedEx, UPS, etc.):

Portland VA Research Foundation
Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
3710 SW U.S. Veterans Hospital Road
Mail Code: R&D 71
Portland, OR 97239

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and*

Maternal Health Outcomes in Developed Countries, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: <https://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2455>

This is to notify the public that the EPC Program would find the following information on *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
 - *For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.*
- *A list of ongoing studies that your organization has sponsored for this indication.* In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted

must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at:

<https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

- KQ 1a. What is the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding?
- KQ 1b. To what extent do the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding differ for subpopulations of women defined by sociodemographic factors (e.g., age, race, ethnicity, socioeconomic status)?
- KQ 1c. To what extent do intervention-related characteristics (e.g., type of breast pump provided—manual or electric; delivery personnel) influence the initiation, duration, and exclusivity of breast feeding?
- KQ 2a. What are the comparative benefits and harms for maternal health outcomes among women who breastfeed for different intensities and durations?
- KQ 2b. To what extent do benefits and harms for maternal health outcomes differ for subpopulations of women defined by age, race, ethnicity, and comorbidity?

Population(s)

KQs 1, 2: Childbearing women and adolescents; we will also search for evidence on subgroups of women defined by age, race, ethnicity, comorbidity, and socioeconomic status (including insurance status and payer type).

Interventions/Exposure

KQ 1: Community, workplace, and health care system-based interventions aimed at promoting and supporting breastfeeding, including the following: health plan benefits, state and federal policies or programs (e.g., WIC programs), hospital implementation of the BFHI, workplace or school-based programs, and others. For studies assessing the effectiveness of BFHI, we will include studies evaluating full and partial implementation (at least 3 steps) of the 10 steps.

KQ 2: Exposure to breastfeeding

Comparators

KQ 1: No intervention (or usual practice); comparisons of two interventions that differ in content or intensity.

KQ 2: No breastfeeding; shorter duration of breastfeeding (e.g., breastfeeding for 1 month vs. 12 months) and/or less intensive breastfeeding (e.g., exclusive breastfeeding vs. mixed feeding or formula feeding)

Outcomes

KQ 1: Rates of breastfeeding initiation; duration and exclusivity of breastfeeding, adverse effects of interventions (e.g., guilt about not breastfeeding, workplace discrimination, and other reported harms)

KQ 2: Postpartum depression, breast cancer, ovarian cancer, osteoporosis, cardiovascular outcomes (e.g., stroke, myocardial infarction), postpartum weight change, type 2 diabetes, hypertension

Timing

KQs 1, 2: We will have no minimum study duration or length of follow up.

Settings

KQs 1, 2: Studies conducted in a developed country ["very high" (KQs 1, 2) and "high" (KQ 1) human development index per the United Nations Development Programme 40

Study Design

KQ 1: Randomized and non-randomized controlled clinical trials; prospective cohort studies with concurrent control groups; systematic reviews; for studies assessing policy or system-level interventions, we will also include pre-post studies with repeated outcome measures before and after the intervention

KQ 2: Randomized and non-randomized controlled clinical trials; cohort studies; case-control studies; systematic reviews

Sharon B. Arnold

Acting Director